

## REMARKS

Applicants thank the Examiner for entering the Amendments of October 14, 2003.

Claims 44-52, 54-57, 59-62, and 65-69 remain in this application. Claims 1-43, 53, 58, 63, and 64 have been cancelled. Claims 70-87 have been withdrawn. Claims 44 and 69 are currently amended. The listing of claims reflects the October 14, 2003, claim amendments.

### **Claim rejections under 35 U.S.C. § 112, first paragraph, enablement**

Claim 69 is rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. Claim 69 has been amended as suggested by the Examiner. Applicants submit that Claim 69, as currently amended, is now in condition for allowance.

### **Claim rejections under 35 U.S.C. § 102**

Claims 44-46, 49, 50-52, 59-61, and 65-69 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Barstad *et al.* (US 5,258,454). Claims 44, 47, 50-52, 56-57, 59-60, and 66-69 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Katz (U.S. Patent No. 4,191,668). Applicants respectfully traverse both rejections for the reasons presented below.

#### **Barstad *et al.*, U.S. Patent No. 5,258,454**

Claims 44-46, 49, 50-52, 59-61, and 65-69 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Barstad *et al.* (US 5,258,454), for reasons of record. In the present Office Action, Claims 44-46, 49, 50-52, 59-61, and 65-69 are rejected on grounds that step (b) of each of independent Claims 44 and 69 allegedly encompasses the case in which a B-cell epitope lacking T-cell epitopes, from a T-dependent antigen, is coupled to the carrier. (Office Action mailed January 2, 2004, page 3, lines 3-7). Applicants respectfully traverse this rejection.

To anticipate a claim, the reference must teach every element of the claim. “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” MPEP § 2131, quoting *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The words of a claim must be given their “plain meaning” unless they are defined in the specification. MPEP § 2111.01.

Barstad *et al.* disclose and claim conjugates of stable nonimmunogenic polymers and analogs of immunogens that possess the specific B cell binding ability of the immunogen but lack T cell epitopes (US 5,258,454: Abstract; Col. 2:65 to Col. 3:3; Claim 1, Col. 11:27-28, emphasis added). In contrast, independent Claims 44 and 69 of the present application both

recite “[a] method of making a non-immunogenic construct comprising at least two copies of an epitope of a T-dependent antigen bound to a pharmaceutically acceptable non-immunogenic carrier . . .” (emphasis added). Step (a) of both claims recites providing a carrier and “an epitope molecule of a T-dependent antigen.” Step (b) of both claims recites “coupling two or more of the epitope molecules” to the carrier, where the antecedent reference for “the epitope molecules” of step (b) is “an epitope molecule of a T-dependent antigen” recited in step (a).

Barstad *et al.* do not expressly disclose an epitope of a T-dependent antigen. Applicants respectfully submit that to construe step (b) of Claims 44 and 69 to encompass coupling a B-cell epitope from a T-dependent antigen lacking T-cell epitopes, as suggested by the Examiner (Office Action, mailed January 2, 2004, page 3, lines 7-9), would be contrary to the plain meaning given to the term “T-dependent antigen” by those of ordinary skill in the art. Applicants conclude that Barstad *et al.* do not expressly or inherently disclose a T-dependent antigen and therefore, does not anticipate Claims 44-46, 49, 50-53, 59-61, and 63-69 because it does not disclose each and every element of these claims. Accordingly, this rejection under 35 U.S.C. § 102(b) is improper and should be withdrawn.

Applicants point out that step (c) of Claims 44 and 69 have been amended as suggested by the Examiner (Office Action mailed January 2, 2004, page 3, lines 12-14). Claims 44 and 69, as amended, now recite in step (c): “subjecting the conjugate preparation to size fractionation to yield a non-immunogenic epitope coupled construct” (added text indicated by underlining).

**Katz, U.S. Patent No. 4,191,668**

Claims 44, 47, 50-52, 56-57, 59-60, and 66-69 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Katz (U.S. Patent No. 4,191,668) for reasons of record. In the present Office Action, Claims 44, 47, 50-52, 56-57, 59-60 and 66-69 are rejected because it is maintained that Katz allegedly teaches the coupling of epitopes of the same nature as the present application. (Office Action mailed January 2, 2004, page 3 lines 18-19).

Applicants point out that that step (a) of independent Claims 44 and 69 has been amended to recite that the carrier is not poly (D-Glu/D-Lys). Support for these amendments is found in the specification on page 31, in Table 1, and on page 48, line 16 to page 49, line 2, in the section entitled “F. Poly (D-Glu/D-Lys).” These amendments obviate the rejection of Claims 44, 47, 50-52, 56-57, 59-60, and 66-69 over Katz, which discloses conjugates of an antigen linked to a D-glutamic acid:D-lysine (D-GL) copolymer. Therefore, this rejection should be withdrawn.

Applicants point out that step (c) of Claims 44 and 69 have been amended as suggested by the Examiner (Office Action mailed January 2, 2004, page 4, lines 3-6). Claims 44 and 69, as amended, now recite in step (c): "subjecting the conjugate preparation to size fractionation to yield a non-immunogenic epitope coupled construct" (added text indicated by underlining).

### **Rejection Under the Doctrine of Obviousness-Type Double Patenting**

Claims 44-47, 49, 52, 60, 65, and 69 are presently rejected under the judicially created doctrine of obviousness-type double patenting as being allegedly unpatentable over Claims 1-9 of US 6,340,460. A terminal disclaimer is required.

Applicants respectfully submit that, when claims are allowed in the present application, a terminal disclaimer will be submitted if it is still deemed necessary.

### **CONCLUSION**

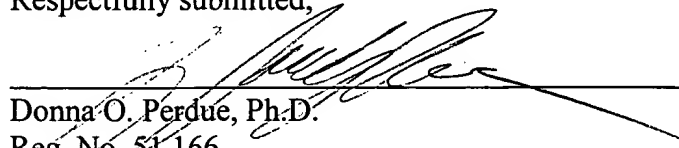
For the reasons set forth herein, Applicants maintain that pending Claims 44-52, 54-57, 59-62, and 65-69 clearly and patentably define the invention, and respectfully request that a timely Notice of Allowance be issued in this case.

Applicants note that a Revocation of Power of Attorney and Change of Correspondence Address was filed on March 1, 2004, and received by OIPE on March 3, 2004. Requests for Change of Address were previously filed on December 23, 2002 and October 21, 2003. Applicants request that the Change of Address be entered into the record.

The present Amendment is being submitted as a required submission for a Request for Continued Examination, which is being submitted with a Petition to Revive under 37 C.F.R. § 1.137(b) and petition fee under 37 C.F.R. § 1.17(m), as well as a Petition for Extension of Time under 37 C.F.R. § 1.136(a) and fee under 37 C.F.R. § 1.17(a)(3). If any additional fees are due, please charge any additional fees, or make any credits, to Deposit Account No. 50-2212.

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Respectfully submitted,

  
Donna O. Perdue, Ph.D.  
Reg. No. 51,166  
Attorney for Applicant

Pillsbury Winthrop LLP  
11682 El Camino Real, Suite 200  
San Diego, CA 92130  
Tel: (858) 509-4093 Fax: (858) 509-4010